ATTACHMENE #1

Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Selections for:

NOINGRED

NUTROPIN_DEPOT

From:

01-NOV-1997 To:

Present

Disclaimer: The information contained in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of adverse drug reactions.

Date: 11/01/00 ISR Num	iber: 3609824-1 Report Type: P	Periodic	dic Company Report#: 095952				Age: 24 MON Gender:		I/FU:
<u>butcome</u>	PT Injection Site Oedema Injection Site Reaction Nos Leukocytosis Pyrexia Rash Erythematous Red Blood Cell Sedimentation Rate Increased White Blood Celt Count Increased	<u>]</u> } {	Report Source Tealth Professional Company Representative	Product Nutropin Depot	Role PS	Manufacturer Genentech Inc	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
ate: 11/01/00 ISR Nun	nber: 3609826-5 Report Type: P	Periodic	Company R	eport#: 095995			Age: 80 YR	Gender: Male	I/FU: I
<u>utcome</u>	PT Injection Site Erythema Injection Site Inflammation Injection Site Oedema Injection Site Pain	Ī	Report Source Health Professional	<u>Product</u> Nutropin Depot	<u>Role</u> PS	Manufacturer Genentech Inc	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
ate: 11/01/00 ISR Nun	iber: 3609827-7 Report Type: P	Periodic	Company R	eport#: 096018			Age: 3 YR	Gender: Female	VFU :
dutcome	<u>PT</u> Headache Nos Injection Site Mass Pyrexia	j	Report Source Health Professional	<u>Product</u> Nutropin Depot Antibiotics Stool Softener	Role PS C C	Manufacturer Genentech Inc	Route SUBCUTANEOUS	Dose 16 MG SC	<u>Duration</u>
Pate: 02/27/01 ISR Nun	iber: 3670973-3 Report Type: [Direct	Company Report#:				Age:	Gender: Female	I/FU:
Outcome ife-Threatening lospitalization -	<u>PT</u> Diabetes Mellitus Insulm-Dependent]	Report Source	Product Nutropin Depot 18 Mg Somatropin	Role	Manufacturer	Route	Dose	<u>Duration</u>
nitial or Prolonged pisability	instant Dependent			Genentech, Inc	PS	Genentech, Inc	SUBCUTANEOUS	.75MG/KG ARMS/LEGS SUBCUTANEO	ous
Date: 05/01/01 ISR Nun	nber: 3714927-7 Report Type: P	Periodic	Company R	Report#: 097634			Age: 9 YR	Gender: Male	I/FU:
Outcome .rfe-Threatening .r	<u>PT</u> Diabetes Mellitus Aggravatcd		Report Source Distributor	<u>Product</u> Nutropin Depot	<u>Role</u> PS	Manufacturer Genentech Inc	* Route SUBCUTANEOUS	<u>Dose</u> 22.5 MG 2/M SC	<u>Duration</u>
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ber: 3755886-0 Report Type: Exp	edited (15-Day) Company F	Report#: 098411			Age: 10 YR	Gender: Male	I/FU: 1
PT Abdominal Pain Upper Dehydration Headache Nos Pyrexia Vomiting Nos Weakness	Report Source Consumer Company Representative	<u>Product</u> Nutropin Depot	<u>Role</u> PS	Manufacturer Genentech Inc	Route SUBCUTANEOUS	<u>Dose</u> 31.5 MG 2/M SC	<u>Duration</u>
ber: 3755887-2 Report Type: Exp	edited (15-Day) Company I	Report#: 098412			Age: 10 YR	Gender: Male	I/FU: I
PT Dehydration Pyrexia Vomiting Nos White Blood Cell Count Increased	Report Source Consumer Company Representative	<u>Product</u> Nutropin Depot Nutropin Depot	Role PS SS	Manufacturer Genentech Inc	<u>Route</u> SUBCUTANEOUS	<u>Dose</u> 31.5 MG,2/M SC	<u>Duration</u>
ber: 3772546-0 Report Type: Peri	odic Company l	Report#: 097634			Age: 9 YR	Gender: Male	VFU: I
PT Diabetes Mellitus Aggravated	Report Source Distributor	<u>Product</u> Nutropin Depot	Role PS	Manufacturer Genenteen Inc	<u>Route</u> SUBCUTANEOUS	Dose 22.5 MG 2/M SC	<u>Duration</u>
	edited (15-Day) Company	Report#: 098873			Age: 18 MON	Gender: Female	I/FU: I
PT Dehydration Diabetes Mellitus Inadequate Control Diarrhoea Nos Irritability Markedly Reduced Dietary Intake Pyrexia Urinary Tract Infection Nos Vomiting Nos	Report Source Health Professional	Product Nutropin Depot Ddavp Thyroxine	Role PS C C	Manufacturer Genentech Inc	Route	<u>Dose</u> 6.75 MG QM S	<u>Duration</u> SC
iber: 3828526-X Report Type: Exp	pedited (15-Day) Company	Report#: 099202			Age: 11 MON	Gender: Male	I/FU: 1
PT Cardio-Respiratory Arrest Loose Stools Respiratory Distress Sepsis Nos Vomiting Nos	Report Source Study Health Professional	<u>Product</u> Nutropin Depot	Role PS	<u>Manufacturer</u>	Route SUBCUTANEOUS	Dose 5.25 MG 2/M SC	<u>Duration</u>
	PT Abdominal Pain Upper Dehydration Headache Nos Pyrexia Vomiting Nos Weakness ber: 3755887-2 Report Type: Exp PT Dehydration Pyrexia Vomting Nos White Blood Cell Count Increased ber: 3772546-0 Report Type: Peri PT Diabetes Mellitus Aggravated ber: 3778233-7 Report Type: Exp PT Dehydration Diabetes Mellitus Inadequate Control Diarrhoea Nos Irritability Markedly Reduced Dietary Intake Pyrexia Urinary Tract Infection Nos Vomiting Nos sher: 3828526-X Report Type: Exp PT Cardio-Respiratory Arrest Loose Stools Respiratory Distress Sepsis Nos	PT Abdominal Pain Upper Dehydration Headache Nos Pyrexia Vomiting Nos Weakness ber: 3755887-2 Report Type: Expedited (15-Day) Company I PT Dehydration Pyrexia Vomiting Nos White Blood Cell Count Increased ber: 3772546-0 Report Type: Periodic PT Diabetes Mellitus Aggravated ber: 3778233-7 Report Type: Expedited (15-Day) Company I PT Dehydration Diabetes Mellitus Aggravated ber: 3778233-7 Report Type: Expedited (15-Day) Company I PT Dehydration Diabetes Mellitus Inadequate Control Diarrhoea Nos Irritability Markedly Reduced Dietary Intake Pyrexia Urinary Tract Infection Nos Vomiting Nos aber: 3828526-X Report Type: Expedited (15-Day) Company I PT Cardio-Respiratory Arrest Loose Stools Respiratory Distress Sepsis Nos Professional	Abdominal Pain Upper Dehydration Headache Nos Pyrexia Vomiting Nos Weakness ber: 3755887-2 Report Type: Expedited (15-Day) Company Report#: 098412 PT Dehydration Pyrexia Vomiting Nos White Blood Cell Count Increased ber: 3775246-0 Report Type: Periodic Diabetes Mellitus Aggravated ber: 3778233-7 Report Type: Expedited (15-Day) Company Report#: 097634 PT Dehydration Diabetes Mellitus Professional Diabetes Mellitus Professional Diamboet Shellitus Inadequate Control Diarnhoea Nos Irritability Markedly Reduced Dietary Intake Pyrexia PT Cardio-Respiratory Arrest Loose Stools Respiratory Distress Sepsis Nos Professional	PT Addominal Pain Upper Consumer Company Headache Nos Pyrexia Vomiting Nos Weakness ber: 3755887-2 Report Type: Expedited (15-Day) Company Report#: 098412 PT Consumer Product Nutropin Depot PS Dehydration Pyrexia Company Pyrexia Company Report#: 098412 PT Consumer Nutropin Depot PS White Blood Cell Count Increased ber: 3772546-0 Report Type: Periodic Company Report#: 097634 PT Diabetes Mellitus Agravated ber: 3778233-7 Report Type: Expedited (15-Day) Company Report#: 098873 PT Dehydration Diabetes Mellitus Professional Profes	PT Abdominal Pain Upper Consumer Consumer Company Report#: 098412 Der: 3755887-2 Report Type: Expedited (15-Day) Company Report#: 098412 PT Dehydration Company Report#: 098412 PT Dehydration Consumer Company Report#: 098412 PT Object State St	PT Objects Melitus Agersentative Nutropin Depot Notes Product Nutropin Depot Notes N	PT Oblobetes Mellitus Aggravated Periodic Company Report#: 097634 Report Source Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC Pytexia Vomiting Nos Weakness Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC Pytexia Vomiting Nos Weakness PT Report Type: Expedited (15-Day) Company Report#: 098412 Agg: 10 YR Gender: Male Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Product Nutropin Depot PS Genentech Inc SUBCUTANEOUS SIS Mod 2/M SC PT Report Source Product Nutropin Depot PS Genentech Inc Subcutaneous Nos Initiability Professional Dadayp C C Thyroxine C Subcutaneous Nos Initiability S

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Date: 12/12/01 ISR Number: 3840288-9 Report Type: Expedited (15-Day) Company Report#: 100372							Gender: Female	I/FU: 1
Outcome Hospitalization - nitial or Prolonged	PT Abdominal Pain Nos Diarrhoea Nos Lethargy Loose Stools Pyrexia Vomiting Nos	Report Source Consumer	Product Nutropin Depot Antituberculosis Medications	Role PS C	<u>Manufacturer</u>	Route	<u>Dose</u>	<u>Duration</u>
Date: 06/03/02 ISR Num	iber: 3928709-4 Report Type: Ex	pedited (15-Day) Company F	Report#: 102636			Age: 12 YR	Gender: Female	VFU: I
Outcome Disability Other	PT Antinuclear Factor Positive Arthralgia Difficulty In Walking Rheumatoid Factor Positive	Report Source Study Health Professional	Product Nutropin Depot Prednisone Neoral Furosemide Atenolol Diltiazem Famotidine Feso4 Calcitriol Lovastatin Zoloft Probenecid Allopurinol	Role PS CCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCC	<u>Manufacturer</u>	<u>Route</u> SUBCUTANEOUS	<u>Dose</u> 40.5 MG Q2WF SC	<u>Duration</u> (
Date: 08/21/02 ISR Num	aber: 3966779-8 Report Type: Ex	pedited (15-Day) Company I	Report#: 103750			Age: 15 YR	Gender: Male	I/FU:
Outcome Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	<u>PT</u> Glioblastoma	Report Source Study Health Professional	<u>Product</u> Nutropin Depot	<u>Role</u> PS	<u>Manufacturer</u>	Route SUBCUTANEOUS	<u>Dose</u> 37.5 MG Q3WI SC	Duration (
Date: 09/05/02 ISR Number: 3972561-8 Report Type: Expedited (15-Day) Company Report#: 103750						Age: 15 YR	Gender: Male	I/FU: 1
Outcome Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	PT Anaplastic Astrocytoma Neuroblastoma Nos	Report Source Study Health Professional	Product Nutropin Depot Testosterone	<u>Role</u> PS C	Manufa _s turer	Route SUBCUTANEOUS	<u>Dose</u> 37.5 MG Q2WI SC	<u>Duration</u> K
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Date: 10/10/02 ISR Numb	per: 3991092-2 Report Type: Dire	ect Company l	Report#: CTU 178499			Age: 9 YR	Gender: Female	I/FU: I
utcome ife-Threatening ospitalization - utial or Prolonged isability	PT Diabetes Mellitus Insulin-Dependent	Report Source	Product Nutropin Depot 18 Mg Genentech, Inc	<u>Role</u> PS	Manufacturer Genentech, Inc	Route SUBCUTANEOUS	Dose 33 MG EVERY 14 DAYS SUBCUTANEO	Duration DUS
Date: 11/07/02 ISR Numl	oer: 4008855-X Report Type: Exp	edited (15-Day) Company I	Report#: 104671			Age:	Gender: Female	I/FU: I
Outcome Other	PT Neoplasm Recurrence Nos	Report Source Consumer	Product Nutropin Depot	<u>Role</u> PS	Manufacturer	Route	<u>Dose</u>	<u>Duration</u>
Date: 11/18/02 ISR Numl	per: 4013159-5 Report Type: Exp	edited (15-Day) Company l	Report#: 102642			Age: 35 YR	Gender: Female	I/FU: I
Outcome Death Ife-Threatening	PT Adrenal Insufficiency Nos Gastroenteritis Viral Nos	Report Source Study Health Professional	Product Nutropin Depot Dilantin Hydrocortisone Prozac L-Thyroxin Ddvap Premarin Provera	Role PS C C C C C C C	<u>Manufacturer</u>	<u>Route</u> SUBCUTANEOUS	<u>Dose</u> 8.4 MG SC	<u>Duration</u>
Date: 12/10/02 ISR Numb	per: 4024753-X Report Type: Exp	edited (15-Day) Company I	Report#: 105035			Age: 11 YR	Gender: Male	I/FU: 1
Outcome Tospitalization - nitial or Prolonged	PT Convulsions Nos Dilatation Ventricular Fall Pneumonia Nos Tibia Fracture	Report Source	Product Nutropin Depot Topamax	Role PS C	Manufacturer	Route SUBCUTANEOUS	<u>Dose</u> 45 MG 12WK S	<u>Duration</u> C
Date: 01/07/03 ISR Number: 4040228-6 Report Type: Expedited (15-Day) Company Report#: 105263							Gender: Male	I/FU: I
outcome ife-Threatening lospitalization - nitial or Prolonged equired ntervention to revent Permanent npairment/Damage	PT Adrenal Insufficiency Nos Blood Glucose Decreased Gastroenteritis Viral Nos Lethargy Loss Of Consciousness	Report Source Study Health Professional	Product Nutropin Depot Cortef Synthroid	Role PS C C	Manufacturer	Route SUBCUTANEOUS	<u>Dose</u> 22.5 MG Q2WK SC	<u>Duration</u> ,
Date: 02/24/03 ISR Number: 4064902-0 Report Type: Expedited (15-Day) Company Report#: 105888						Age: 25 YR	Gender: Female	I/FU: I
<u>utcome</u> ospitalization - itial or Prolonged	PT Bradycardia Nos Hypokalaemia Nausea							
	rausca							

Pharyngolaryngeal Pain Supraventricular Tachycardia Vomiting Nos

Report Source Health

Product Nutropin

Manufacturer Role

Route

<u>Dose</u>

Duration

Professional Depot(Somatropin) PS

PS

SUBCUTANEOUS

Age: 13 YR

67.5 MG, SINGLE,

Gender: Male

SUBCUTANEOUS

Date: 03/12/03 ISR Number: 4075452-X Report Type: Expedited (15-Day) Company Report#: 200076

PT Death Unexplained Vomiting Nos

Report Source Health Professional

Product Nutropin

Soln

Depot(Somatropin) Pwdr & Solvent, Injection Soln

Role Manufacturer

Route

Dose

VFU: 1

Duration

16 5 MG

Date: 03/21/03 ISR Number: 4081934-7 Report Type: Expedited (15-Day) Company Report#: 096413

Role Manufacturer

Age: 10 YR Gender: Female I/FU: I

Outcome Hospitalization -Initial or Prolonged Disability

Outcome

Death

PT Blood Thyroid Stimulating Hormone Increased Diabetes Mellitus Nos Diabetic Ketoacidosis

Report Source Study Health

Professional

Product Nutropin Depot (Somatropin) Pwdr & Solvent, Injection

PS

Route

<u>Dose</u>

Duration

SUBCUTANEOUS 33 MG, QD, SUBCUTANEOUS